

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Omeprazole, Pantoprazole and Esomeprazole in treatment of laryngopharyngeal reflux

Protocol summary

Summary

60 patients with signs and symptoms of laryngopharyngeal reflux meeting will enter the study. The patients will be allocated randomly to three subgroups. The first, second and third group will receive Omeprazole, Pantoprazole, and Esomeprazole, respectively, for three months by the dose suggested in previous studies. The severity of symptoms and signs will be evaluated using predesigned data sheets and self-instructed forms and based on laryngoscopic findings prior to and three months after treatment. The drugs are provided in boxes without any labels. The data reviewer is also blinded to the patients groups. Finally the symptoms scores and laryngoscopic findings will be compared with previous findings.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050133277N2**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

Mehrdad Jafari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1628

Email address

m-jafari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Otorhinolaryngology research center, Tehran University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Omeprazole, Pantoprazole and Esomeprazole in treatment of laryngopharyngeal reflux

Public title

Comparison of the effect of Omeprazole, Pantoprazole and Esomeprazole in treatment of laryngopharyngeal reflux

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: presence of symptoms of laryngopharyngeal reflux; presence of signs of laryngopharyngeal reflux in pharyngeal examinations
Exclusion criteria: Recent treatment with antireflux drugs; history of surgery on Stomach and esophagus; history of connective tissue diseases; any benign or malignant lesions of larynx; receiving antiinflammatory drugs either systemic or inhalational

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2016-11-12, 1395/08/22

Ethics committee reference number

IR.TUMS.VCR.REC.1395.983

Health conditions studied**1****Description of health condition studied**

Gastro-oesophageal reflux disease

ICD-10 code

K21

ICD-10 code description

Gastro-oesophageal reflux disease

Primary outcomes**1****Description**

Globus sensation

Timepoint

before treatment then 3months later

Method of measurement

History

2**Description**

number of days with reflux

Timepoint

before treatment then 3months later

Method of measurement

history

3**Description**

Posr nasal discharge

Timepoint

before treatment then 3months later

Method of measurement

history

4**Description**

Vocal cord erythema

Timepoint

Befaoe and three months after treatment

Method of measurement

Laryngoscopy

5**Description**

Supraglottic edema

Timepoint

Before and three months after treatment

Method of measurement

Laryngoscopy

6**Description**

Severity of cough

Timepoint

before treatment then 3months later

Method of measurement

history

7**Description**

Cough after meals or when lying down

Timepoint

before treatment then 3months later

Method of measurement

history

8**Description**

Hoarseness

Timepoint

Before and three months after treatment

Method of measurement

Questionnaire

9

Description

Heartburn and acid rising feeling

Timepoint

before treatment then 3months later

Method of measurement

history

10

Description

Difficulty swallowing

Timepoint

before treatment then 3months later

Method of measurement

taking history

11

Description

Difficult breathing

Timepoint

before treatment then 3months later

Method of measurement

taking history

12

Description

Interarytenoid edema

Timepoint

Before and three months after treatment

Method of measurement

Laryngoscopy

Secondary outcomes

empty

Intervention groups

1

Description

tab Esomeprazole 40mg, po, BD for 3 months

Category

Treatment - Drugs

2

Description

Tab Pantoprazole 40 mg, po, BD for 3 months

Category

Treatment - Drugs

3

Description

Tab Omeprazole 40 mg, po, BD for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Nadia Shafiei

Street address

Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Science

Full name of responsible person

Dr. Masoud Yoonesian

Street address

Qods St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Tehran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nadia Shafiei

Position

Resident Assistant of Otolaryngology

Other areas of specialty/work

Street address

4th floor, Valiasr hospital, imam khomeini hospital complex, Keshavarz Blvd.

City

Tehran

Postal code

1419733141

Phone

+98 21 61190

Fax

Email

shafiei_nadia@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrdad Jafari

Position

Assistant Professor of Otolaryngology Head and Neck Surgery

Other areas of specialty/work

Street address

Department of otolaryngology, Imam Khomeini hospital complex, Keshavarz Blvd.

City

Tehran

Postal code

1419733141

Phone

+98 21 6658 1628

Fax

Email

mehrdadj82@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nadia Shafiei

Position

Resident Assistant of Otolaryngology

Other areas of specialty/work

Street address

Imam khomeini hospital complex, Keshavarz Blvd.

City

Tehran

Postal code

1419733141

Phone

+98 21 61190

Fax

Email

shafiei_nadia@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty